

### **III. Remarks**

#### **A. Status of the Application**

Claims 26-30, 33-35, and 53-64 are pending. Claims 26-30 and 33-35 were previously pending. Claims 53-64 have been added. No claims are presently canceled. Reconsideration of this application in light of the above amendments and the following remarks is respectfully requested.

As a preliminary matter and as mentioned in Applicants' previous response, while the Office Action Summary indicates that claim 33 is rejected, there is no rejection of claim 33 set forth in the Office Action. Accordingly, Applicants submit that claim 33 is in condition for allowance.

Applicants appreciate the courtesies extended by the Examiner during the telephone interview on May 20, 2008. Claims 26, 28, and 29 were discussed. In particular, the rejection of the claims over the prior art was discussed. No exhibits were shown in the interview. The Sava patent (U.S. Patent No. 5,658,286) and Gelbard patent (U.S. Patent No. 5,397,363) were discussed generally with regards to the relevant claim language. An agreement was reached at the time of the interview that the combination of the Sava and Gelbard patents does not disclose all the elements of claim 26. Specifically, it was agreed that the references do not disclose a crossbar with a hardenable media as recited. The remarks and claim amendments of the present paper are in accordance with the interview.

#### **B. Claim Rejections – 35 U.S.C. §103**

Claims 26 and 29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the combination of U.S. Patent No. 5,658,286 to Sava ("the Sava patent") and U.S. Patent No. 5,397,363 to Gelbard ("the Gelbard patent").

As the PTO recognizes in MPEP § 2142:

... The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. If the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness...

In the present application, a prima facie case of obviousness does not exist for claims 26 and 29 for at least the reasons set forth below.

35 U.S.C. §103(a) provides, in part, that:

“A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time of the invention was made to a person having ordinary skill in the art . . .”  
(emphasis added)

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated.

With respect to independent claim 26, however, even when combined the Sava and Gelbard patents fail to disclose all of the recited limitations. For example, claim 26 recites “a first support structure, configured to extend through the portals in the first and second bone anchors; a second support structure, configured to be attached to the spine; and a cross bar, which connects the first support structure to the second support structure to form an orthopedic construct; wherein the cross bar is attached to the first and second support structures subcutaneously; and wherein at least the cross bar comprises a media that is hardenable while the support structure is positioned within the body of a patient.” As discussed below, the Sava and Gelbard patents do not disclose such limitations.

The Response to Arguments section of the Final Office Action states:

“The claim also requires a cross bar that attaches to a first and second support structures. Noting the support structures as stated above in Sava, a cross bar (36) connects the first (Gelbard equivalent 28) and second support structure (bone anchors in Gelbard).”

However, as discussed and agreed upon during the telephone interview on May 20, 2008, it is clear that the cross bar 36 of the Gelbard patent does not meet the recited limitations of the cross bar of claim 26. Specifically, the cross bar 36 is a “rectangular shaped rigid plate” and does not comprise a hardenable media as required by claim 26. Col 4, l. 18. Accordingly, even when combined, the Sava and Gelbard patents fail to disclose all of the recited limitations of independent claim 26.

Thus, for at least these reasons a *prima facie* case of obviousness has not been established with respect to independent claim 26. Claim 29 depends from and further limits claim 26. Accordingly, Applicants request that the §103 rejection of claims 26 and 29 over the Sava and Gelbard patents be withdrawn.

Claims 30 and 35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Sava and Gelbard patents as applied to claim 26 in further view of U.S. Patent No. 4,743,260 to

Burton (“the Burton patent”). Claims 30 and 35 depend from and further limit claim 26. As shown above, a *prima facie* case of obviousness has not been established with respect to claim 26 with the Sava and Gelbard patents. The Burton patent does not affect this deficiency. Accordingly, for at least the same reasons a *prima facie* case of obviousness has not been established with respect to claims 30 and 35. Therefore, Applicants request that the §103 rejection of claims 30 and 35 over the Sava, Gelbard, and Burton patents be withdrawn.

Claims 27 and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Sava and Gelbard patents as applied to claim 26 in further view of U.S. Patent No. 6,336,930 to Stalcup et al. (“the Stalcup patent”). Claims 27 and 28 depend from and further limit claim 26. As shown above, a *prima facie* case of obviousness has not been established with respect to claim 26 with the Sava and Gelbard patents. The Stalcup patent does not affect this deficiency. Accordingly, for at least the same reasons a *prima facie* case of obviousness has not been established with respect to claims 27 and 28. Therefore, Applicants request that the §103 rejection of claims 27 and 28 over the Sava, Gelbard, and Stalcup patents be withdrawn.

### C. New Claims

New claims 53-62 are patentable over the Sava and Gelbard patents and other cited references because each of the claims recites one or more combinations of elements that are not disclosed or suggested in the cited references. For example, new independent claim 53 recites:

53. A prosthetic stabilization system for subcutaneous assembly within a patient's body, the system comprising:
- a first pair of bone anchors, each comprising a distal end and a proximal end, the proximal end including a head with a portal extending therethrough;
  - a second pair of bone anchors, each comprising a distal end and a proximal end, the proximal end including a head with a portal extending therethrough;
  - a first elongated support structure, sized to extend between a first vertebrae and a second vertebrae and through the portals in the first pair of bone anchors;
  - a second elongated support structure, sized to extend between the first vertebrae and the second vertebrae and extend through the portals in the second pair of bone anchors; and
  - a crossbar attachable to the first and second support structures;

wherein at least the crossbar comprises a media that is hardenable while the crossbar is positioned within the patient's body.

Claims 54-62 depend from and further limit claim 53 including additional limitations and combinations not disclosed or suggested in the cited references. Accordingly, claims 54-62 are patentable over the cited references.

New claims 63-64 are also patentable over the Sava and Gelbard patents and other cited references because each of the claims recites one or more combinations of elements that are not disclosed or suggested in the cited references. For example, new independent claim 63 recites:

63. A prosthetic stabilization system for subcutaneous assembly within a patient's body, the system comprising:  
a first spinal stabilization member comprising an inflatable balloon with a proximal end, a distal end, and a flexible wall defining an interior cavity extending between the proximal and distal ends, wherein the first stabilization member is sized to extend between a first and second vertebrae;  
a second spinal stabilization member comprising an inflatable balloon with a proximal end, a distal end, and a flexible wall defining an interior cavity extending between the proximal and distal ends, wherein the second stabilization member is sized to extend between the first and second vertebrae;  
a crossbar attachable to the first and second spinal stabilization members, the crossbar comprising an inflatable balloon with a proximal end, a distal end, a flexible wall defining an interior cavity extending between the proximal and distal ends, wherein the crossbar has a first deflated state with a first maximum diameter and a second inflated state with a second maximum diameter, the second maximum diameter being greater than the first maximum diameter;  
a first connector for attaching the crossbar to the first stabilization member, the first connector comprising a first aperture having a first diameter for receiving the crossbar and a second aperture having a second diameter for receiving the first stabilization member, the second aperture being generally perpendicular to the first aperture, wherein the first diameter of the first aperture is less than the second maximum diameter of the crossbar; and  
a second connector for attaching the crossbar to the second stabilization member, the second connector comprising a third aperture having a third diameter for receiving the crossbar and a fourth aperture having a fourth diameter for receiving the second stabilization member; the third aperture being generally

perpendicular to the fourth aperture; wherein the third diameter of the third aperture is less than the second maximum diameter of the crossbar;

wherein the inflatable crossbar is elongated to extend through the first aperture of the first connector and the third aperture of the third connector in its first deflated state such that inflation of the crossbar to its inflated state while extending through the first and third apertures secures the crossbar to the first and second connectors.

Claim 64 depends from and further limits claim 63 including additional limitations and combinations not disclosed or suggested in the cited references. Accordingly, claims 63 and 64 are patentable over the cited references.

#### IV. Conclusion

It is believed that all matters set forth in the Office Action have been addressed and that all of the pending claims are in condition for allowance. An indication of allowance of the pending claims is respectfully requested.

Should the Examiner deem that an interview with Applicant's undersigned attorney would expedite consideration of this application, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

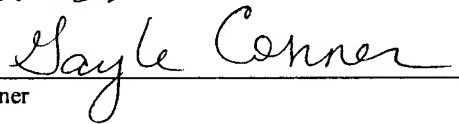


Gregory P. Webb

Registration No. 59,859

Date: 6-2-08  
HAYNES AND BOONE, LLP  
Customer No. 46333  
Telephone: 972-739-8641  
Facsimile: 214-200-0853  
R-198381\_3.DOC

I hereby certify that this correspondence is being filed with  
the United States Patent and Trademark Office via EFS-Web  
on 6-2-08.



Gayle Conner